K011768

455 Route 30, Imperial, PA 15126
(724) 695-1890 Fax (724) 695-1892
Toll Free No. 1-800-633-8080
Specialists in *precise* temperature control

AUG - 3 2001

510 (K) Summary

We at Thermo-Electric Company believe our Thermo-Therapy products (Models TT-101, TT-201, and TT-202) are virtually identical to the equivalent sized Fluidotherapy models – with the exception that our TT-101 equivalent to Fluidotherapy Model T-11, although the same in size and cellulose capacity, is For Professional Use Only – not home use – and the cautions are so provided.

This 510 (K) is being submitted by:

Thermo-Electric Company
455 Route 30
Imperial, PA 15126
Telephone Number (724) 695-1890
Fax Number (724) 695-1892

Lawrence E. Madson, Jr. – June 1, 2001

Thermo-Electric Company is an Ohio Corporation having been in business since 1924 and is also the manufacture of many other products for the use in the professional physical and occupational therapy market.

The substantially equivalent (SE) product to our Thermo-Therapy is 510 (K) K871802 and 510 (K) K896817 both product code LSB and commonly known as Fluidotherapy.

The Fluidotherapy type devices describe a process where ground cellulose is held in animated suspension by heated air blowing through a screen filter (often called the Fluidizing Bed) and held captive by a housing and flexible velcro tightening sleeves.

This process then allows for a hand, wrist, foot, ankle, and on larger units, the lower leg to be immersed in the heated cellulose.

The now fluidized cellulose gently and warmly massages the extremity resulting in improved blood circulation, wound healing, comfort, etc.

Thermo-Electric's Thermo-Therapy devices have identical technology characteristics to that of Fluidotherapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Mr. Lawrence E. Madson, Jr.
Vice President
Thermo-Electric Company
455 Route 30
Imperial, Pennsylvania 15126

Re: K011768
Trade/Device Name: Thermo-Therapy - Models TT-101, TT-201, and TT-202
Regulatory Class: Unclassified
Product Code: LSB
Dated: July 13, 2001
Received: July 25, 2001

Dear Mr. Madson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K 011768

Device Name: Thermo-Therapy – Models TT-101, TT-201, and TT-202

Indications for Use:

Increase of Local Blood Circulation.

Treatment of Range of Motion when combined with exercise.

Treatment for minor pain and stiffness of non—rheumatoid arthritis.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011768